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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,355	11/08/2001	Alexander B. Rossi	375462-002US.	5867

37509 7590 08/22/2005

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EXAMINER

LI, QIAN JANICE

ART UNIT	PAPER NUMBER
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1633

DATE MAILED: 08/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/053,355	Applicant(s) ROSSI, ALEXANDER B.	
	Examiner Q. Janice Li, M.D.	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37-50 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 37-50 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/27/05</u> . | 6) <input type="checkbox"/> Other: ____ |

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DETAILED ACTION

The response filed 5/31/05 is acknowledged. No claim is amended. Claims 37-50 are pending, and under current examination.

Unless otherwise indicated, previous rejections that have been rendered moot in view of a convincing argument will not be reiterated. The arguments in 5/31/05 response would be addressed to the extent that they apply to current rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 37-50 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the remarks, the applicant argued that the end products generated by the claimed methods are functional mast cells. The applicant also argued the specification describes characteristics of functional mast cells, which are consistent with the criteria used by those skilled in the art.

In response, the term "functional" is a functional limitation. MPEP instructs, "A FUNCTIONAL LIMITATION IS AN ATTEMPT TO DEFINE SOMETHING BY WHAT IT DOES, RATHER THAN BY WHAT IT IS (E.G., AS EVIDENCED BY ITS SPECIFIC STRUCTURE OR SPECIFIC INGREDIENTS)" (MPEP 2173.05 g). "A FUNCTIONAL LIMITATION MUST BE EVALUATED AND CONSIDERED, JUST LIKE ANY

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OTHER LIMITATION OF THE CLAIM, FOR WHAT IT FAIRLY CONVEYS TO A PERSON OF ORDINARY SKILL IN THE PERTINENT ART IN THE CONTEXT IN WHICH IT IS USED". In the instant case, mast cells have various functions, e.g. responding to physiologic activation or non-physiological activation (such as depicted in instant figures 6A-6B); and different types of mast cells have different functions as well, such as tryptase enzymatic activity and hexosaminidase enzymatic activity. Skin mast cells (MCTC) react to compound 48/80 and substance P while lung mast cells (mainly MCT) do not (*Matsushima et al*, column 1, page 5). Moreover, the function of mature and immature mast cells differs. Since the specification fails to define the term "functional mast cell", fails to teach precisely what type of mast cell may be produced from the culture, and the prior art of record had suggested that the cytokine-induced differentiation would only produce a population of immature mast cells with functions largely uncertain. Hence, the newly introduced claim limitation "functional mast cells" would not fairly convey to a person of ordinary skill in the pertinent art what would be the function of the end product of instant claimed invention, and what the limitation encompasses, but rather, the new limitation adds ambiguity as to which "function" it refers to, and thus the metes and bounds of the claims are uncertain.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 37-50 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for generating cultivated mast cells, does not reasonably provide enablement for generating *functional* mast cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

In the remarks, the applicant first argued that the method described in *Matzushima* is different from the instant claimed method. *Matzushima* follows the method described in *Saito*, which uses a different process and growth factor combinations.

In response, a brief review of the prosecution history would find that the applicant fails to show that mast cells produced by instantly claimed method indeed differ from the mast cells produced by *Saito et al.* As noted previously, the prior art cells differ from the claimed cells only by their method of manufacture. However, the claimed method of making mast cells would not distinguish them over the mast cells taught by the prior art. Moreover, the claims fully embrace the conditions taught by *Saito et al.* (e.g. the combination of SCF and IL-6), and the specification fails to teach the type and the maturity of the end product of instantly claimed method, thus, one can not distinguish the end product of instantly claimed method with that of *Saito et al.*

The applicant then argued that it is largely irrelevant whether the mast cells produced by the instant method are immature or mature because claims do not require such a distinction.

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In response, the characteristics of the end product are particularly relevant to the functional limitation in the preamble of the claims. This is because the state of maturity of the mast cells is closely associated with their function. For example, *Matzushima* teaches concerning the state of the art pertinent to cultivated human mast cells, "THESE RESULTS SUGGEST THAT THE PRESENT CULTURE CONDITION IS **NOT** SUFFICIENT TO DEVELOP **FUNCTIONALLY** MATURE MCTC"; and "THE PRESENT STUDY SUGGESTS THAT CORD BLOOD-DERIVED HUMAN CULTURED MAST CELLS ARE **IMMATURE** BOTH MORPHOLOGICALLY AND **FUNCTIONALLY**, AND THAT SCF AND IL-6 ARE NOT CAPABLE OF PROMOTING A COMPLETE MATURATION OF HUMAN CULTURED MAST CELLS". *Matzushima* concluded "THE FACTOR(S) REQUIRED FOR CELLS TO BE FULLY MATURE IN VITRO REMAIN UNKNOWN" (column 1, page 12, emphasis added). Since the instant disclosure fails to teach otherwise, and fails to shed light on the unknown factors in the art, it would require undue experimentation for the skilled intending to practice the invention to determine what functions are possessed by the mast cells produced by instantly claimed method. The specification fails to disclose evidence contrary to the findings of *Matsushima et al.* Accordingly, the invention does not appear to be enabled in the absence of clarification of the contradictory evidence found in the references.

The applicant additionally argued the instant specification describes the combination of IL-6 and SCF generates human mucosal airway type mast cells, the response to secretagogues, and the conclusion in the abstract of *Matzushima* supports the full scope of the claimed methods.

In response, as an initial matter, it is noted that instant claims are not limited to the IL-6 induced mast cell differentiation; they encompass *any cytokine suitable* for differentiating the progenitor cells into mast cells. As to the teaching of *Matzushima*, the

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abstract starts with "CORD BLOOD-DERIVED HUMAN MAST CELLS CULTURED IN THE PRESENCE OF SCF AND IL-6 ARE A MIXTURE OF MCTC AND MCT AT VARIOUS RATIOS" and continued with "THEY WERE SO IMMATURE THAT WE COULD NOT DISTINGUISH MCT AND MCTC FROM THEIR ULTRACSTRUCTUAL MORPHOLOGY". Thus, the response to secretagogues alone does not change the aforementioned conclusion, and does not support the full scope of instant claims.

Therefore, for reasons of record and set forth *supra*, the rejection stands.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Q. Janice Li** whose telephone number is 571-272-0730. The examiner can normally be reached on 9:30 am - 7 p.m., Monday through Friday, except every other Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Dave T. Nguyen** can be reached on 571-272-0731. The fax numbers for the organization where this application or proceeding is assigned are **571-273-8300**.

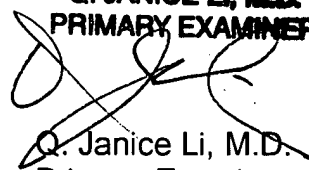
Any inquiry of formal matters can be directed to the patent analyst, **Dianiece Jacobs**, whose telephone number is (571) 272-0532.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at **800-786-9199**.

Q. JANICE LI, M.D.
PRIMARY EXAMINER

Q. Janice Li, M.D.
Primary Examiner
Art Unit 1633

QJL

August 18, 2005